FSIS Facts

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Food Safety and Inspection Service

Food Additives

The role of food additives has become more prominent in recent years, due in part to the increased production of prepared, processed, and convenience foods. At the same time, consumers, scientists, and others have raised questions about the necessity and safety of these substances.

Although limited amounts of food additives are necessary to guarantee adequate food supplies for a growing population, their use is strictly controlled by laws that assure consumers that foods are safe to eat and accurately labeled.

Under the Food, Drug, and Cosmetic Act, the term "food additive" is defined as any substance which "results or may reasonably be expected to result--directly or indirectly--in its becoming a component or otherwise affecting the characteristics of any food." The definition includes any substance used in producing, processing, treating, packaging, transporting, or storing food, including any source of radiation intended for such uses.

Regulating Additives

Before any substance can be added to food, its safety must be assessed in a stringent approval process.

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture shares responsibility with the Food and Drug Administration (FDA) for the safety of food additives. All additives are initially evaluated for safety by FDA. When an additive is proposed for use in meat and poultry products, it must also be evaluated by FSIS, as provided in the Federal Meat Inspection Act and the Poultry Products Inspection Act. Although FDA guidelines are used to evaluate the safety of additives, FSIS may apply even stricter standards that take into account the unique characteristics of meat and poultry products. Several years ago, for instance, permission was sought to use sorbic acid in meat salads. Although sorbic acid was an approved food additive, permission to use it in meat salad was denied because such usage could mask spoilage caused by food poisoning organisms.

Additives are never given permanent approval. FDA and FSIS continually review the safety of approved additives to determine if approvals should be modified or withdrawn.

Food Safety Laws

The first major law governing food was the 1906 Federal Food and Drug Act, sometimes referred to as the Pure Food Law. It prohibited the sale of adulterated food and drugs in interstate commerce. The act was renamed the Federal Food, Drug, and Cosmetic Act in 1938 when it was extensively revised to account for changes in medical science and food technology. Among the new law's provisions was a requirement for truthful labeling of additives.

Food Additives

The 1958 Food Additives Amendment to the Food, Drug, and Cosmetic Act provided the first specific regulation of food additives. Approval of new food additives was required before they could be marketed, and the responsibility for proving their safety was placed on the manufacturer. To use or market a substance, a company must file a petition with FDA showing that tests prove the substance is safe. If the substance is approved as an additive, FDA prescribes the types of food in which it can be used and labeling directions and may also prescribe the maximum quantity that can be used.

The Food Additives Amendment exempted two groups of additives from the testing and approval process. The first is the list of substances which experts have classified "generally recognized as safe" (GRAS). This list includes substances such as flavorings and spices which are considered harmless because past extensive use has produced no known harmful effects. Also exempted from testing were "prior sanctioned substances" which FDA or USDA had approved for use in food prior to passage of the 1958 Food Additives Amendment. Additives can be removed from the lists, however, if tests indicate the substances are not safe for human consumption. All substances previously listed as GRAS are being reviewed to assure that they meet current food safety standards. Eventually all the substances will either be affirmed as GRAS or removed from GRAS status.

The 1960 Color Additive Amendments brought all colors--natural and synthetic--under the Food, Drug and Cosmetic Act. Color additives may not be used to deceive consumers or to conceal blemishes or inferiorities in food.

The Food Additives Amendment and the Color Additives Amendments include the so-called Delaney Clause, which prohibits the approval of an additive "if it is found to induce cancer when ingested by" people or animals, or "if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in" people or animals. Any substance found to cause cancer would be regulated under the general safety provisions of these laws, as well as by the Delaney Clause.

The inspection laws and FSIS regulations require certain information on labels of meat and poultry products so that consumers will have complete information about a product. In most cases, ingredients must be listed on the product label in order by weight, from the greatest amount to the least. Spices, flavorings, and colors may be listed as such without naming each one.

These labeling requirements are important in helping consumers make informed judgments about the food they eat.

Why Are Additives Used?

Food additives have been used for thousands of years. In prehistoric times, salt was probably used to preserve meat and fish. Our ancestors also found that large amounts of sugar helped preserve fruit and that cucumbers could be preserved in a vinegar solution. Today, salt, sugar, and corn syrup are by far the most widely used additives.

The purposes of additives are as varied as the foods in which they are used. Additives prevent salad dressing from separating, salt from becoming lumpy, and packaged goods from spoiling on the grocery shelf. They keep cured meat products safe to eat and give margarine its yellow color. The addition of vitamins and minerals to milk, flour, cereals, and breads was a key factor in the disappearance of diseases such as goiter, rickets, pellagra, and beriberi in the United States over the last 50 years.

What Additives Are Used?

Additives are generally classified as either direct or indirect.

Direct additives are those substances added directly to foods for a specific purpose, and, by law, they must be named on labels on meat and poultry products. The meat and poultry inspection regulations specify how these additives can be used.

Antioxidants, such as propyl gallate and butylated hydroxyanisole (BHA), are approved for use in retarding rancidity in dry sausage, rendered animal or vegetable fat, fresh pork sausage, and dried meats. Ascorbic acid and citric acid are antioxidants used in curing to accelerate color fixing or to preserve color during storage. Citric acid also helps protect flavor and increases the effectiveness of other antioxidants.

Preservatives and curing agents such as table salt, sugar, benzoic acid, and sodium nitrite help prevent food spoilage. The limited use of nitrite is permitted to cure products like bologna, frankfurters, bacon, and salami and prevent the growth of organisms that cause botulism in humans.

Binders and extenders--including cereals, nonfat dry milk, and soy protein products--are permitted in such items as sausages and meat patties to bind together ingredients and extend processed products. Potassium sorbate is permitted in margarine and in the solution used to coat sausage casings to retard growth of mold. Proteolytic enzymes, such as bromelin, ficin, and papain, are permitted for the purpose of tenderizing beef cuts.

Although FSIS and FDA have approved these additives for safety, their use is not required in most cases. In fact, a number of food manufacturers limit the use of additives or avoid using them altogether. Persons who are concerned about additives or who must avoid certain substances in their diets should consult product labels to learn the names of any direct additives used in the product.

Another group of additives is classified as indirect. These substances may be present in food in very small amounts as a result of some phase of production, processing, storage, and packaging. For instance, packaging materials may become indirect additives when minute amounts of substances making up the packaging material diffuse into the food.

Indirect additives are also subject to regulation for safety. FSIS and FDA work with the industry to ensure that materials used in processing and packaging meat and poultry products are safe, perform their intended function, and comply with food safety laws. This joint effort will continue as new information becomes available.